PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2004/042723	21.12.2004	30.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61M39/26, F16L29/02

Applicant
VASOGEN IRELAND LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Björklund, A

Telephone No. +49 89 2399-7310

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2004/042723

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ in written format

   ☐ in computer readable form

   c. time of filing/furnishing:

   ☐ contained in the international application as filed.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	14-21
	No:	Claims	1-13,22-30
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-30
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

2. Citations and explanations

   see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV
Lack of unity of invention

1. The separate groups of inventions are:

Group I) Claims 1-10:
Claims 1-10 define a valve assembly comprising a male luer end portion, a female luer end portion and a channel for female luer end portions, valve means, biasing means and actuating means extending into the male luer end portion and coupled to the valve means to actuate the valve means when a female luer end portion of a medical accessory is coupled with the male luer end portion.

Group II) Claims 11-30:
Claims 11-30 define a medical dispensing device comprising a body having a chamber therein to contain a fluid material and a valve assembly in fluid communication with the chamber, the valve assembly having a male coupling member for engaging a female coupling member on a medical accessory to form a fluid coupling between the medical dispensing device and the medical accessory, the valve assembly being configured such that it opens when the male coupling member is connected with a female coupling member.

1.1. They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The common matter between the two groups of inventions is at most a valve assembly having a male coupling member and openable by the connection with a female coupling member. Said matter is clearly not novel over the general common knowledge. There are also several documents disclosing said matter, see for example US2003/136932, fig. 2.

The features of each group of invention which are not common with the other group of invention address different objective technical problems, namely:
I) A way of providing a valve assembly which can be connected to any medical device with a male luer connector to provide it with an automatically closing male luer connector (claims 1-10).

II) A way of providing a medical dispensing device having a valve assembly and a male connector closing upon disconnection with a female connector (claims 11-30).

Therefore, the two groups of inventions do not present the same or corresponding technical features (Rule 13.2 PCT). Consequently, the application as a whole does not present a single general inventive concept as required by Rule 13.1 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:
D1 : US 2003/136932 A1 (DOYLE MARK C) 24 July 2003 (2003-07-24)
D2 : US 6 299 132 B1 (WEINHEIMER JACEK M ET AL) 9 October 2001 (2001-10-09)
D3 : US 2003/111623 A1 (ENERSON JON R) 19 June 2003 (2003-06-19)
D4 : EP 0 791 371 A (INDUSTRIE BORLA SPA) 27 August 1997 (1997-08-27)
D5 : US-A-6 106 502 (RICHMOND ET AL) 22 August 2000 (2000-08-22)
D6 : WO 01/03756 A (IMPLANT INNOVATIONS, INC) 18 January 2001 (2001-01-18)
D7 : US 2002/066715 A1 (NIEDOSPIAL JOHN J ET AL) 6 June 2002 (2002-06-06)
D8 : US-A-5 738 144 (ROGERS ET AL) 14 April 1998 (1998-04-14)
D9 : US 2003/060804 A1 (VAILLANCOURT VINCENT L) 27 March 2003 (2003-03-27)

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-13, 22-30 is not new in the sense of Article 33(2) PCT.

Group I)

3.1. The document D1 discloses (the references in parentheses applying to this document):
A valve assembly comprising a male luer end portion (fig. 6), a female luer end portion and a channel from the transfer of fluids between the male and the female luer end portions (fig. 6, left side), valve means movable between a closed position and an open position (fig. 6, item 42), biasing means for biasing the valve means toward the closed position (fig. 6, item 14), and actuating means extending into the male luer end portion and coupled to

the valve means to actuate the valve means when a female luer end portion of a medical accessory is coupled with the male luer end portion (fig. 6, item 42)

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

3.2. The document D5 (figs. 1-4 & 18) also discloses the features of claim 1 (Article 33(2) PCT)

Group II)

3.3. The document D5 discloses (the references in parentheses applying to this document):

A medical dispensing device comprising a body having a chamber therein to contain a fluid material (fig. 10, item 190), a valve assembly in fluid communication with the chamber (items 194 & 196, col. 7, lines 6-10), the valve assembly having a male coupling member for engaging a female coupling member on a medical accessory to form a fluid coupling between the medical dispensing device and the medical accessory (fig. 1, item 34), the valve assembly further comprising flow control means operable to control fluid flow through the male coupling member, the flow control means being operable to be displaced by the female coupling member to open the male coupling member when the female coupling member is operatively connected therewith, the flow control means being operable to be displaced by the female coupling member to close the male coupling member when the female coupling member is disconnected therefrom (figs. 1 & 4, items 20 & 30, col. 4, lines 52-55).

The subject-matter of claim 11 is therefore not new (Article 33(2) PCT).

3.4. The document D6 (fig. 2) also discloses the features of claim 11 (Article 33(2) PCT).

3.5. The document D8 discloses (the references in parentheses applying to this document):

A medical dispensing device comprising a body having a chamber therein to contain a fluid

material and a valve assembly in fluid communication with the chamber (figs. 1-5, items 48 & 54, col. 2, lines 45-54), the valve assembly having a male coupling member for engaging a female coupling member on a medical accessory to form a fluid coupling between the medical dispensing device and the medical accessory, the male coupling member including a projection and an outer valve member movable relative to the projection (items 70 & 86), the projection and the outer valve member forming a fluid channel therebetween, a sheath portion encircling the projection and spaced therefrom to form a passage to receive the female coupling member (item 40), the valve member being engageable with the female coupling member and movable relative to the projection to open the fluid channel when the female coupling member is connected with the male coupling member (col. 4, lines 8-17).

The subject-matter of claim 22 is therefore not new (Article 33(2) PCT).

3.6. The document D9 (figs. 1-5) also discloses the features of claim 22 (Article 33(2) PCT).

Groups I & II)

4. Dependent claims 2-10, 12-21 and 23-30 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). The reason therefore is that claims 2-10, 12-21 and 23-30 merely define trivial design options of the valve means, the actuating member and the housing which have no special technical effects and which are known in the art (D1, figs. 6, 9-12 and 14-23; D2, figs. 1-14; D3, figs, 1-7; D4, figs. 1-6 and 11-12; D5, figs. 1-4, 9, 18; D6, fig. 2; D7, figs. 1-5; D8, figs. 1-5; D9, figs. 1-7).

Re Item VI
Certain documents cited

Certain published documents

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*

WO2004/060474	22/07/2004	19/12/2003	31/12/2002

Re Item VII

Certain defects in the international application

5. Claims 1, 11 and 22 are not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

6. Documents D1, D5 and D8 are not mentioned in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII

Certain observations on the international application

Group II)

7. Claims 11 and 22 have been drafted as independent claims and have at least partly overlapping scope. Drafting such a plurality of independent claims with overlapping scope makes it impossible to clearly delimit the subject matter which could represent the invention for which protection is sought, so that the claims 11-30 as a whole fail to comply with the clarity and conciseness requirements of Article 6 PCT.